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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,398	10/24/2003	Lee A. Core	106586-172 US2	2513
84317	7590	11/23/2009		
NMT Medical, Inc 27 Wormwood Street Boston, MA 02210			EXAMINER	
			TRUONG, KEVIN THAO	
			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			11/23/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/693,398

**Applicant(s)**

CORE, LEE A.

**Examiner**

Kevin T. Truong

**Art Unit**

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 13-18, 20, 21 and 26-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 13-18, 20-21, and 26-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/17/2009 has been entered.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 13-15, 26-31, 38, 45-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumoto (US 7182753).

Note in figures 12 and 13 of Matsumoto, a conduit (1) having inner layer (7) and outer layer (8), wherein the durometer of the inner layer (7) is capable of being greater than the durometer of the outer layer (8); wherein the circumference of the inner layer (7) is discontinuous so as to form a discontinuity (at 74) and is non-overlapping; and the circumference of the outer layer (8) is continuous and extends (located at 82) between the discontinuity (at 74) of the inner layer (7);

Art Unit: 3734

wherein the different elastic sections (7,8) comprising resilient material and capable of allowing the conduit (54) to expand temporarily in the radial direction.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 16-18, 20-21, 32-44, and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (US 5318588) in view of Matsumoto (US 7182753).

Horzewski et al. disclose the invention as claimed including a conduit for insertion into a body through which another device passes with two layers bonded together and the inner layer having a higher durometer than the outer layer (col. 7, line 40-41, 51-54; ref. 5-7, 11 and 14, Fig. 1A-1D), the inner layer being discontinuous by means of a slit (see ref. 13) and the outer layer being continuous (see Fig. 1B), the conduit being an introducer sheath or a catheter (obvious variations of one another), a medical device with an outer diameter greater than the inner layer diameter for insertion through the conduit (see bulge in Fig. 2A-2F) and wherein the conduit expands as the medical device passes through it, and a method of using the device (see Fig. 2A-2F). Horzewski et al. do not disclose a conduit having an inner layer forms a discontinuity and is non-overlapping and also a portion of the outer layer extends between the

discontinuities. Matsumoto teaches in figures 12 and 13 that it is known in the surgical art to have a conduit having an inner layer forms a discontinuity and is non-overlapping and also a portion of the outer layer extends between the discontinuity (as state in the 102 rejection above) .

At least for this reason, it would have been obvious to one having ordinary skill in the art to have modified Horzewski et al. with an inner layer forms a discontinuity and is non-overlapping and also a portion of the outer layer extends between the discontinuity, as taught by Matsumoto in order to allow the conduit to expand radially as a medical device is passed through it.

As to claims 40-41 and 43-44, Horzewski et al. disclose the invention substantially as claimed except for the inner layer having one of the other geometric formations to aid in expansion, the medical device being a stent, blood clot filter, or occluder, the device being foldable for delivery through the conduit and in a second manner different from the first manner for retrieval. Stents, blood clot filter, and occluder are well-known devices to be inserted through a conduit and into a lumen of a body such as a blood vessel. It is also well-known that these devices are folded into a smaller collapsed diameter so that they can be easily inserted into a delivery device. The expanded, deployed diameter of a stent, blood clot filter, and occluder is well-known to be larger than its initial diameter. Therefore, it would have been obvious to one having ordinary skill at the time of the invention to have modified Horzewski et al. with the medical device being a stent, blood clot filter, or occluder in order to be inserted into a

body lumen. Howzeski et al. also disclose a conduit that has third and fourth types of section in a circumferential direction. Although the layers are oriented with one layer outside the other layer, they are still comprised of first through fourth types of sections in a circumferential direction (see Fig. 1 above).

As to claims 53-56, Horzewski et al. disclose the invention substantially as claimed except for the inner layer having one of the other geometric formations to aid in expansion, the medical device being a stent, blood clot filter, or occluder, the device being foldable for delivery through the conduit and in a second manner different from the first manner for retrieval. The other geometric formations are obvious variation of having a slit and/or an overlapping section that would obtain the same results of expanding the inner layer of the conduit. Stents, blood clot filter, and occluder are well-known devices to be inserted through a conduit and into a lumen of a body such as a blood vessel. It is also well-known that these devices are folded into a smaller collapsed diameter so that they can be easily inserted into a delivery device. The expanded, deployed diameter of a stent, blood clot filter, and occluder is well-known to be larger than its initial diameter. Therefore, it would have been obvious to one having ordinary skill at the time of the invention to have modified Horzewski et al. with a different geometric formation of the inner layer of the conduit and with the medical device being a stent, blood clot filter, or occluder in order to be inserted into a body lumen.

***Response to Arguments***

5. Applicant's arguments filed 09/17/2009 have been fully considered but they are not persuasive. Applicant's arguments with respect to claims 1-5, 13-18, 20-21, and 26-56 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin T. Truong whose telephone number is 571-272-4705. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734

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